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SEP 28 1994

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Re: CPI Ventak PRx AICD System

FDA Docket No. 94E-0315

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,407,288 issued October 4, 1983. The application was filed on August 16, 1994, under Title II of Public Law 98 - 417, the Drug Price Competition and Patent Term Restoration Act of 1984.

In my letter of August 22, 1994, to you, I noted that it was not apparent that Peter Forrest, the registered patent attorney who filed the application for patent term extension on behalf of the licensee-marketing applicant, was authorized to act on behalf of the beneficial owner of the patent, the Estate of Mieczyslaw Mirowski, at the time the application for patent term extension was filed. On September 19, 1994, pursuant to an Order to Show Cause, the patent owner submitted documents attesting that Peter Forrest applied for the application for patent term extension with the consent of the patent owner, the Estate of Mieczyslaw Mirowski, at the time the application for patent term extension was filed.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC § 156(d)(2)(A).

C.E. Van Horn

Charles E. Van Horn
Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Peter Forrest
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